ALBAcheck® BGS Monoclonal Control

510(k) Summary (as required by 21 CFR 807.92(a))

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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Date: August 30, 2019

Premarket Notification 510(k)
ALBAcheck® BGS Monoclonal Control
510(k) Summary (as required by 21 CFR 807.92(a)

B. Name/Common Name of Device:

ALBAcheck® BGS Monoclonal Control

Alba Bioscience Limited Product Code:

Z271U

Proprietary Name:

ALBAcheck® BGS Monoclonal Control

Device Classification Name:

Quality control kit for blood banking reagents

Device Class:

ALBAcheck® BGS Monoclonal Control is a class II IVD medical device according to the stipulations of 21 CFR 864.9650.

Regulation Number and Product Code:

Regulation Number: 864.9650

FDA Product Code: KSF

Classification Panel:

Hematology

C. Predicate(s):

Immucor Monoclonal Control (510(k) Number: BK070013, Product Code: KSF).

D. Device Description:

ALBAcheck® BGS Monoclonal Control is supplied in a 10 mL glass vial with dropper, containing 10 mL of product, and is packaged as either single vial pack or a ten-vial pack. The composition of ALBAcheck® BGS Monoclonal Control is similar to the formulation to ALBAclone® Blood Grouping Reagents.

ALBAcheck® BGS Monoclonal Control is intended as a negative control for ALBAclone® Blood Grouping Reagents.

False positive test results are rarely seen with low-protein reagents such as ALBAclone® Blood Grouping Reagents. However, spontaneous agglutination may occur due to samples with positive direct antiglobulin test (DAT), cold agglutinins, or abnormal serum proteins. A negative result with a test that was performed concurrently with a similar reagent serves as a control. Fung, MK Editor. AABB Technical Manual, Nineteenth Edition. Bethesda, MD: AABB, 2017 states that 6 - 10% BSA may be used as a negative control for low-protein reagents. ALBAcheck® BGS Monoclonal Control is formulated in a similar way to Alba Bioscience's ALBAclone Blood Grouping Reagents (but without the anti-body component) and is intended for use a control with these reagents.

E. Indications for Use:

For *in vitro* diagnostic use only.

ALBAcheck® BGS Monoclonal Control is intended for use as a negative control in conjunction with ALBAclone® Blood Grouping reagents (where referenced in the reagent IFU).

F. Substantial Equivalence Comparison and Discussion:

Table 1 below presents a direct comparison of the subject device, ALBAcheck® BGS Monoclonal Control and the US legally marketed predicate device, Immucor Monoclonal Control (510(k) Number: BK070013, Product Code: KSF).

Table 1 – Device Comparison

Characteristic	Predicate Device Immucor Monoclonal Control 510(k) Number: BK070013	Subject Device ALBAcheck® BGS Monoclonal Control
Device Classification Name	Quality control kit for blood banking reagents	Same as predicate
Product Code	KSF	Same as predicate
US FDA Classification	Class II	Same as predicate
US FDA Regulation Number	864.9650	Same as predicate
US FDA Review Panel	Hematology	Same as predicate
Intended Use	Monoclonal Control is intended to be used as control for Immucor low protein Blood Grouping Reagents and Gamma-clone Blood Grouping Reagents used in Slide, Tube and Microplate Tests	ALBAcheck® BGS Monoclonal Control is intended for use as a negative control in conjunction with ALBAclone® Blood Grouping reagents (where referenced in the reagent IFU).
Intended Use Clarification	The device is intended for use as a control reagent with specified low protein blood grouping reagents supplied by the same manufacturer.	Same as predicate
Product Composition	Formulation similar to Immucor Blood Grouping Reagents	Formulation similar to ALBAclone Blood Grouping Reagents
Intended User(s)	*In vitro* diagnostic (IVD) device for professional use only.	Same as predicate
Manufacturer	Immucor Inc	Alba Bioscience Limited

Table 1 demonstrates that the subject device ALBAcheck® BGS Monoclonal Control, and the US legally marketed predicate, Immucor Monoclonal Control (510(k) Number: BK070013 are substantially equivalent with regards to the following parameters: classification, intended use, design, and mode of action.

Comparator testing performed using ALBAcheck® BGS Monoclonal Control and Immucor Monoclonal Control has demonstrated 100% concordance between test results from 105 samples analysed using both devices. It was therefore concluded that the safety and effectiveness of ALBAcheck® BGS Monoclonal Control is substantially equivalent to the legally marketed predicate. Further details of the study are provided in the Section G. Performance Testing.

G. Performance Testing:

Performance evaluation studies were carried out to demonstrate that the performance of ALBAcheck® BGS Monoclonal Control is substantially equivalent to the US legally marketed predicate and that the product is safe and effective for its intended use.

Comparator Testing

Two lots of ALBAcheck® BGS Monoclonal Control were used to test 105 samples using all the test methods detailed in the ALBAclone Blood Grouping Reagent IFUs subject of the proposed expanded intended use of Z271U (detailed in Table 1 below). Testing was performed concurrently on the same test samples using the predicate.

The results of comparator testing showed 100% concordance between ALBAcheck® BGS Monoclonal Control and the legally marketed predicate. It was concluded that the two products are substantially equivalent with respect to safety and effectiveness and ALBAcheck® BGS Monoclonal Control suitable for its intended use as a control for ALBAclone Blood Grouping Reagents specified in Table 2 below.

Table 2

Product Name	Product Code	BL STN Number	Existing/Additional Indications for Use (compared to ALBAcheck® BGS Reagent Control for Anti-D)
ALBAclone Anti-D *alpha*	Z031U	125304	Existing intended use
ALBAclone Anti-D *beta*	Z036U	125304	Existing intended use
ALBAclone Anti-D *delta*	Z039U	125313	Existing intended use
ALBAclone Anti-D *blend*	Z041U	125314	Existing intended use
[1] ALBAclone Anti-D *fusion*	Z043U	125314/50	Existing intended use
ALBAclone Anti-C^w	Z106U	125601	Addition subject of this 510k
ALBAclone Anti-e	Z096U	125600	Addition subject of this 510k
ALBAclone Anti-C	Z064U	125600	Addition subject of this 510k
ALBAclone Anti-c	Z083U	125306	Addition subject of this 510k
ALBAclone Anti-E	Z073U	125305	Addition subject of this 510k
ALBAclone Anti-Fy^b	Z154U	125637	Addition subject of this 510k
ALBAclone Anti-M	Z171U	125308	Addition subject of this 510k
ALBAclone Anti-N	Z176U	125309	Addition subject of this 510k
ALBAclone Anti-Lu^b	Z223U	125312	Addition subject of this 510k
ALBAclone Anti-K	Z132U	125572/3	Addition subject of this 510k
ALBAclone Anti-Jk^a	Z162U	125568/3	Addition subject of this 510k
ALBAclone Anti-Jk^b	Z166U	125569/4	Addition subject of this 510k
ALBAclone Anti-P1	Z202U	125573/3	Addition subject of this 510k

Reactivity with Spontaneously Agglutinating Samples

Positive reactivity has been observed with spontaneously agglutinating samples (both naturally occurring and simulated samples) and ALBAcheck® BGS Monoclonal Control. A summary of the results is provided in Table 3 overleaf.

Table 3 Results from testing spontaneously agglutinating samples with ALBAcheck® BGS Monoclonal Control, using different test methods.

Sample ID	ALBAcheck® BGS Monoclonal Control		
	Immediate Spin	15 min, 18-24 °C	15 or 30 min, 37 °C
1	Negative	Positive	Negative
2	Positive	Positive	Positive
3	Positive	Positive	Negative
4	Positive	Positive	Negative
5*	Positive	Positive	Negative
6*	Positive	Positive	Positive
7*	Positive	Positive	Negative
8*	Positive	Positive	Positive
9*	Positive	Positive	Positive
10*	Positive	Positive	Positive
11*	Positive	Positive	Positive
12*	Positive	Positive	Positive
13*	Positive	Positive	Positive

Samples 1 to 4 were naturally occurring samples tested at a Reference Laboratory.

*Samples 5 to 13 were constructed samples manufactured internally at Alba Bioscience to simulate spontaneously agglutinating red blood cells. The 37 °C incubation test technique for these sample used a 15 minutes incubation

H. Summary of Software:

ALBAcheck® BGS Monoclonal Control has not been designed with any software device components or accessories, nor is it intended to be used in combination with any software device. Consequently, this section is not applicable.

I. Compliance with FDA Guidance and Consensus Standards:

ALBAcheck® BGS Monoclonal Control has not been designed or manufactured in conjunction with any US FDA consensus standards.

J. Conclusion:

ALBAcheck® BGS Monoclonal Control is a Class II IVD medical device according to 21 CFR 864.9650. This product is substantially equivalent to the US legally marketed predicate, Immucor Monoclonal Control (510(k) Number: BK070013)

Substantial equivalence has been demonstrated via a comparator study, and subsequent analysis of results obtained.

Performance Evaluation testing has confirmed that ALBAcheck® BGS Monoclonal Control is safe and effective, and suitable for its intended use as a control for the ALBAclone Blood Grouping Reagents listed in Table 2.